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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,745	10/17/2003	Knut Meyer	CL2314 US NA	3903
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23906 7590 10/04/2006

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/688,745	Applicant(s) MEYER ET AL.	
Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 June 2006.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,5,9,11,14,16,17,19 and 23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5,9,11,14,16,17,19 and 23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 October 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/13/06.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

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DETAILED ACTION

1. Claims 1, 2, 5, 9, 11, 14, 16, 17, 19, and 23 are pending and under consideration in this Office Action.
2. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' amendment to the claim filed on 06/11/2006.
3. The rejection of claims 1, 2, 5, 9, 11, 14, 16, 17, 19, and 23 under 35 U.S.C. 112, first paragraph, as failing to meet the enablement requirement has been withdrawn in view of applicants' amendment to the claims filed on 06/11/2006.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1, 2, 5, 9, 11, 14, 16, 17, 19, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the phrase "nucleic acid molecule encoding a polypeptide having hydroxycinnamoyl CoA hydratease/lyase activity selected from the group consisting of SEQ ID NOs: 5, 58, 59, 60, 62, 63 and 64" renders the claim vague and indefinite because these sequences are not amino acid sequences but are instead nucleotide sequences. The metes and bounds of the claim are unclear since it is not certain if applicants are actually referring to amino acid sequences or nucleotide sequences. Dependent claims 2, 5, 9, 11, 14, and 16 are also rejected because they do not correct the defect of claim 1.

Amending the claims to recite a nucleic acid molecule selected from the group consisting of SEQ ID NOs: 5, 58, 59, 60, 62, 63 and 64, which encodes a 4- hydroxycinnamoyl CoA hydratease/lyase may overcome the rejection.

Similarly, claim 14 is vague and indefinite for reciting the phrase "nucleic acid molecule encoding a polypeptide having UDP-glucosyltransferase activity selected from the group

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consisting of SEQ ID NOs: 65, 66, and 67". The metes and bounds of the claim are unclear since it is not certain if applicants are actually referring to amino acid sequences or nucleotide sequences. Dependent claims 19 and 23 are also rejected because they do not correct the defect of claim 17.

Amending the claims to recite a nucleic acid molecule selected from the group consisting of SEQ ID NOs: 65, 66, and 67, which encodes a UDP-glucosyltransferase may overcome the rejection.

For examination purposes, the amended claims are assumed to encompass any nucleic acid encoding any 4-hydroxycinnamoyl CoA hydratase/lyase of any amino acid sequence and structure and any nucleic acid encoding any UDP-glucosyltransferase of any amino acid sequence and structure.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 5, 9, 11, 14, 16, 17, 19, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Because the claims are assumed to encompass any nucleic acid encoding any 4-hydroxycinnamoyl CoA hydratase/lyase of any amino acid sequence and structure and any nucleic acid encoding any UDP-glucosyltransferase of any amino acid sequence and structure for reasons stated above in the rejection under 35 U.S.C. 112, second paragraph, the claims stand rejected for failing to comply with the written description as stated in the previous Office Action.

The claims are drawn to a method comprising the use of a genus of nucleic acids encoding a 4-hydroxycinnamoyl-CoA hydratase/lyase (HCHL) expression cassette, a genus of nucleic acids encoding HCHLs, a genus of tissue specific promoters from any nucleic acid encoding any protein involved in cellulose synthesis, and a genus of nucleic acid molecules encoding para-hydroxybenzoic acid UDP-glucosyltransferases. The scope of each genus

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includes many members with widely differing structural, chemical, and physiochemical properties including widely differing nucleotide or amino acid sequences. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exist.

The specification discloses an HCHL expression cassette of SEQ ID NO: 30 (Example 3); a tissue specific promoter of SEQ ID NOs: 26, 43, 44, 45, 46, 49, 81, 82, or 83 (Examples 4, 6-9); a nucleic acid molecule of SEQ ID NOs: 5, 6, 58, 59, 60, 61, 62, 63, or 64 encoding a 4-hydroxycinnamoyl-CoA hydratase/lyase (Examples 1-2, 8, and 9); and para-hydroxybenzoic acid UDP-glucosyltransferase of SEQ ID NOs: 65, 66, or 67. However, the specification does not describe and define any structural features and nucleotide or amino acid sequences commonly possessed by members of each genus. Furthermore, recitation of "HCHL expression cassette", "HCHL", "tissue-specific promoter", and "para-hydroxybenzoic acid UDP-glucosyltransferase" do not define any structural features and nucleotide or amino acid sequences commonly possessed by each genus. Thus, one skilled in the art cannot predict and visualize or recognize the identity of the members of each genus for use in the claimed method.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of nucleic acids encoding a HCHL expression cassette, a genus of nucleic acids encoding HCHLs, a genus of tissue specific promoters from any nucleic acid encoding any protein involved in cellulose synthesis, and a genus of nucleic acid molecules encoding para-hydroxybenzoic acid UDP-glucosyltransferases for use in the claimed method to selectively produce para-hydroxybenzoic acid in plant stem tissue.

Amending the claims to recite a nucleic acid molecule selected from the group consisting of SEQ ID NOs: 5, 58, 59, 60, 62, 63 and 64, which encodes a 4-hydroxycinnamoyl Co A hydratease/lyase; and amending the claims to recite a nucleic acid molecule selected from the group consisting of SEQ ID NOs: 65, 66, and 67, which encodes a UDP-glucosyltransferase may

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overcome the rejection.

Conclusion

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER